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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,670	02/15/2001	Yaping Zhu	540541-2029	2237

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EXAMINER

WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/02/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/784,670

Applicant(s)

ZHU ET AL.

Examiner

Sandra Wegert

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

**Status of Application, Amendments, and/or Claims**

The Information Disclosure Statement, submitted 29 November 2002, has been entered into the record as Paper 9. The amendment filed 20 March 2003 (Paper No. 11) has been entered. Claims 2, 4 and 5 have been amended.

The Terminal Disclaimer filed on 20 March 2003 (Paper 12) disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,475,468 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claims 1-14 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Withdrawn Objections And/Or Rejections**

**Claim Objections**

The objections to Claims 2, 4 and 5 for reciting non-elected inventions is *withdrawn*. The reasons for this objection were set forth in the previous Office Action (Paper 8, 19 November 2002, page 9). Applicants have amended claims 2, 4 and 5 to recite only the elected Invention.

**Claim Rejections**

***35 U.S.C. § 112, second paragraph.***

The rejection of Claims 8, 9, 11, 12 and 14 for being indefinite (e.g., "anti-solvent"), as set forth at p. 3 of the previous Office Action (Paper No. 4, 31 December, 2001), is *withdrawn*. Applicants have argued that "anti-solvent" is a term that is well known and understood in the art (see for example the Abstracts in: US Patents 6,299,906 and 6,517,840).

Similarly, the rejection of Claims 8 and 9 for being indefinite (e.g., "a critical pressure and temperature"), as set forth at p. 3 of the previous Office Action (Paper No. 4, 31 December, 2001), is *withdrawn*. Applicants argue (p. 5-6, Paper 7, 21 August 2002) that the choice of conditions specified in the claims would be obvious to one of skill in the art, and that furthermore, US Patent 4,582,731 describes the critical conditions used for the methods of the instant Invention and has been incorporated by reference into the Specification.

***Non-Statutory Double-Patenting.***

The rejection of Claims 1-14 under the judicially created doctrine of obviousness-type double patenting is *withdrawn*. The reasons for this rejection were set forth in the previous Office Action (Paper 8, 19 November 2002, page 9), because it appeared that Claims 1-13 of U.S. Patent No. 6,475,468 claimed similar subject matter as the instant Application. Applicants have submitted a Terminal Disclaimer to US Patent 6,475,468 (Paper 12, 20 March 2003).

**New Objections and/or Rejections**

***Information Disclosure Statement***

Reference numbers 3 and 4 on the Information Disclosure Statement PTO 1449 were lined through by the Examiner because: there was provided no Authors, no reference numbers and no publication dates. Furthermore, References 3 and 4 may contain privileged information that should not be publicly disclosed.

***Claim Rejections - 35 USC § 102- Prior Art***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3-14 are rejected under 35 USC § 102 (b) and (e) as being anticipated by Hora, et al, in Patent No. 5,730,769 (1998). The claims in Patent 5,730,769 read on a polysaccharide polymer construct comprising a medicament; the claims read on a large variety of medicaments, including insulin. Since claims 1 and 3-14 of the instant Application recite a

polysaccharide polymer construct comprising a medicament, the Claims anticipate a multitude of polysaccharide polymers and medicaments. This rejection can be overcome by specifying well-defined components of the construct.

Similarly, claims 1 and 3-14 are rejected under 35 USC § 102 (b) and (e) as being anticipated by Baichwal, A. in Patent No. 5,478,574 (1995). The claims in Patent 5,478,574 read on a heteropolysaccharide polymer construct comprising a medicament; the medicaments recited include *hormones*. Since claims 1 and 3-14 of the instant Application recite a polysaccharide polymer construct comprising a medicament, the Claims anticipate a multitude of polysaccharide polymers and medicaments. This rejection can be overcome by specifying well-defined components of the construct.

Claims 1, 2 and 6-14 are also rejected under 35 USC § 102 (b) and (e) as being anticipated by Otagiri, et al in Patent No. 5,302,399 (1994). The claims in Patent 5,302,399 read on an alginic acid polysaccharide polymer construct comprising a medicament; the medicaments recited include  $\beta$ -blockers. Method steps for synthesis recite alginic acid viscosities of 100 cps, which read on approximately 4% alginic acid by weight. Since claims 1, 2 and 6-14 of the instant Application read on or recite an alginic acid polymer construct comprising a medicament, the Claims anticipate a multitude of polysaccharide polymers and medicaments. This rejection can be overcome by specifying well-defined components of the construct, as well as specific conditions used in the synthesis of the construct.

***Claim Rejections - 35 USC § 112, second paragraph, indefiniteness.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.**

Claims 3, 4 and 5 are rejected under 35 U.S.C. 112, -second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 5 are objected to under 37 C.F.R. § 1.75(b) as being duplicate claims.

One of the duplicate claims should be canceled or otherwise amended to delimit a different scope of the invention. Applicant's attention is also directed to M.P.E.P. § 706.03(k).

Claim 3 is rendered indefinite because it defines a medicament by molecular weight (e.g., "1 K Dalton") without specifying the method by which the molecular weight was obtained; it is not known therefore, how pure the polypeptide is or how accurate the measurements were. Amending independent claims to recite a method of molecular weight measurement would be remedial.

### ***Conclusion***

Claims 1-14 are rejected for the reasons outlined above.

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***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

5/30/03

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER